

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3721. Misbranding of cortisone acetate tablets. U. S. v. Edward Strauss. Plea of nolo contendere. Fine of \$500 and sentence of one year in prison; prison sentence suspended and defendant placed on probation for one year. (F. D. C. No. 31279. Sample Nos. 25354-L, 25355-L.)

INFORMATION FILED: January 2, 1952, District of New Jersey, against Edward Strauss, manager of Strauss Pharmacy, Elizabeth, N. J.

ALLEGED SHIPMENT: On or about March 2 and 5, 1951, from the State of New Jersey into the State of New York.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the article failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: April 25, 1952. A plea of nolo contendere having been entered, the court imposed a fine of \$500 and a sentence of one year in prison. The court suspended the prison sentence and placed the defendant on probation for one year.

3722. Misbranding of Histamist. U. S. v. 7 Display Cartons * * *. (F. D. C. No. 32436. Sample No. 35436-L.)

LIBEL FILED: January 14, 1952, Southern District of Iowa.

ALLEGED SHIPMENT: On or about March 28, 1951, by the Histamist Corp., from Chicago, Ill.

PRODUCT: 7 display cartons, each containing 12 1 $\frac{3}{4}$ -ounce bottles, of *Histamist* at Ottumwa, Iowa. Analysis disclosed that the article was a solution containing methapyrilene hydrochloride and desoxyephedrine hydrochloride.

LABEL, IN PART: (Bottle) "Histamist An Antihistaminic and Decongestant nasal solution."

NATURE OF CHARGE: Section 505 (a), the article was a drug which may not be introduced or delivered for introduction into interstate commerce since it was a new drug and an application filed pursuant to Section 505 (b) was not effective with respect to the drug.

Misbranding, Section 502 (a), the following statements appearing on the display carton were false and misleading since the article was not an effective treatment for the conditions referred to: "Histamist * * * for Head Colds — Sinus Misery * * * Helps resist infection * * * Check constant sore throats, infections, etc. from sinus drip Use Histamist for Direct Relief * * * Do you have splitting sinus headaches? Smokers catarrh? Use Histamist for prompt relief * * * Do you have head colds, sinusitis * * * sinus headaches? Use Histamist Check head cold and sinus misery in minutes Direct nasal sprays, for Direct relief."

DISPOSITION: March 10, 1952. Default decree of condemnation and destruction.